



December 22, 2017

ImpediMed Limited
% Reuben Lawson
Senior Director, Regulatory Affairs and Clinical
ImpediMed Inc.
5900 Pasteur Court, Unit 125
Carlsbad, CA 92008

Re: K172507
Trade/Device Name: SOZO™
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: DSB
Dated: November 21, 2017
Received: November 22, 2017

Dear Reuben Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K172507

Device Name

SOZO™

Indications for Use (Describe)

The SOZO Fluid Status Monitor is intended for adult patients living with heart failure.

This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

ImpediMed's SOZO™ system

Submitter:

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Australia

Phone: 760 585 2104

Facsimile: 760 804 9245

Contact Person: Reuben Lawson

Date Prepared: August 17, 2017

Name of Device: SOZO™

Common or Usual Name: Body Fluid Analyzer

Regulation Number: 21 CFR§820.2770

Regulation Name: Impedance Plethysmograph

Regulatory Class: II

Product Code: DSB

Predicate Device: ImpediMed Limited's IMED-Z (K142503)

Reference Devices: NMT, Inc's ZOE Fluid Status Monitor (K133301)

ImpediMed Limited's SOZO™ (K172122)

ImpediMed Limited's SFB7 (K052319)

Device Description

The SOZO™ system consists of a connected hand and footplate with built-in stainless steel electrodes, paired with an Android tablet over Bluetooth connection. An app ("SOZOapp"), supplied with the tablet, controls the functionality of the hardware and supplies the bioimpedance measurement data to a database ("SOZOhub") contained within the hospital/facility network.

Measurements require the patient to make contact with bare hands and feet on stainless steel electrodes. The measurement takes about 30 seconds, during which the SOZO™ system measures small quantities of electrical energy (200µA RMS) across 256 frequencies, spaced logarithmically from 3kHz to 1000kHz. Established algorithms are used to analyze data and calculate extracellular fluid impedance levels for left and right sides of the body, and present the impedance levels for the

clinician to review. These scores facilitate the clinician's noninvasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

Intended Use/Indications for Use

The SOZO Fluid Status Monitor is intended for adult patients living with heart failure.

This device is intended for use, under the direction of a physician, for the noninvasive monitoring of patients with fluid management problems suffering from heart failure. Data from the device should be considered in conjunction with other clinical data.

Summary of Technological Characteristics

Bioimpedance is the technological principle for both the subject and predicate devices. The subject and predicate devices are based on the following same fundamental technological elements:

- Use of electrodes to take measurements; two 'drive' and two 'sense' channels are used to measure each side of the body;
- 'Drive' channels deliver very low levels of current (200 μ A RMS);
- 'Sense' channels measure current (I), voltage (V) and phase angle (Ph), and calculates three bioimpedance parameters: impedance (Z), resistance (R) and reactance (Xc) to calculate the impedance values and estimate extracellular fluid

Minor technological differences exist between the subject and predicate devices:

- SOZO™ utilizes a revamped external housing using stainless steel electrodes for taking bioimpedance measurements;
- SOZO™ utilizes more frequencies (256 frequencies logarithmically spaced from 3kHz to 1000kHz);
- SOZO™ is wall powered rather than battery powered;
- Data is stored in and accessed from a local database (SOZOhub) utilizing separate software installed on a network connected PC.
- SOZO™ is controlled through an Android app on a supplied tablet, which is paired to the SOZO™ hardware over Bluetooth connection, and connects with the local database over Wi-Fi.

Purpose of 510(k)

The purpose of this 510(k) is to clear the design changes presented in the SOZO™ system and indications for use presented in the SOZObeat measurement module.

These changes are intended to provide a faster, more streamlined customer experience with a more aesthetically pleasing design.

Performance Data

The SOZO™ system has gone through appropriate testing per design controls to confirm the new design's functionality and performance.

Electrical safety/EMC: testing was performed according to the requirements set forth in IEC 60601 (subparts -1, -1-2, and -1-6). It was determined that the SOZO™ device meets electrical safety and EMC requirements, and CB certificate was granted for the system.

Software V&V: the same level of concern software documentation as the predicate device was created and testing performed in accordance with ISO 62304. The software was verified and validated to meet acceptance criteria and perform as intended.

Biocompatibility: testing was performed by an accredited third party according to the requirements set forth in ISO 10993 for a low risk, limited contact device. It was determined that the SOZO™ system passed biocompatibility testing with no failures reported.

Comparative performance: a test fixture was used to create multiple fixed impedance loads representing different ‘humans’. Using this test fixture, a SOZO™ system was compared against a IMED-Z system to verify correlation in outputs. The SOZO system showed a very strong correlation ($r > 0.99$) compared to the cleared ZOE system.

Functional performance: multiple SOZO™ systems were tested for design reliability by repeatedly placing weights on the components that encounter the most physical stress. Testing showed that the system is expected to remain functional throughout its intended life.

Conclusions

The SOZO™ system has the same intended uses /indications, and similar technological characteristics, and principles of operation as its predicate device. In addition, the technological differences between the SOZO™ system and its predicate device raise no new or different issues of safety or effectiveness. Design controls demonstrate that the SOZO™ system is as safe and effective as the cleared device version. Thus, the SOZO™ system is substantially equivalent.